IN UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
AT KNOXVILLE

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	No. 3:15-CR-27-TAV-DCP
SYLVIA HOFSTETTER,	)	
COURTNEY NEWMAN, and	)	
CYNTHIA CLEMONS,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

All pretrial motions in this case have been referred to the undersigned pursuant to 28 U.S.C. § 636(b) for disposition or report and recommendation regarding disposition by the District Court as may be appropriate. Defendants Hofstetter, Newman, and Clemons ask [Doc. 444] the Court to exclude or limit the expert testimony of the Government's four medical experts, arguing that their proposed testimony is not reliable or relevant. They also ask the Court to exclude or limit the use of the Government's DOMEX report, contending that the methodology used in compiling the data contained therein is deficient on its face. The Government responds [Doc. 477] that a hearing to test the methodology of its medical experts is unnecessary because the Defendants do not raise a *Daubert* issue, its medical experts may properly testify about their opinions on patient files that they have reviewed, and its DOMEX report is admissible as a summary of other admissible evidence.

For the reasons discussed herein, the Court finds the parties agree that the Government's medical experts cannot extrapolate to the treatment of patients at the pain clinics as a whole, based solely upon their review of a limited number of patient files selected by the Government. Thus, a "*Daubert* hearing," at which the Government's experts must defend their

methodology, is not necessary. The Court also finds that the DOMEX report is not subject to a *Daubert* analysis, because it is not an expert report.

I. BACKGROUND AND POSITIONS OF THE PARTIES

On March 10, 2015, law enforcement officers executed search warrants at two pain clinics associated with this case and seized approximately 6,300 patient files.[1] In preparation for trial, the Government retained the following medical experts: Dr. James Wilke, an anesthesiologist and the medical director of a pain management clinic; Dr. John Blake, a medical doctor, president and medical director of a pain management clinic, and assistant professor at the University of Tennessee Department of Medicine; Dr. Michael Carter, a retired professor at the University of Tennessee Health Science Center, with a doctorate in nursing practice; and Mr. Gary Tooley, a physician assistant and associate professor at Christian Brothers University [Doc. 477, pp.5-7]. The Government selected and provided a number of patient files, seized from the pain clinics in this case, for each of these experts to review: Dr. Wilke reviewed 55 files; Dr. Blake reviewed 79 files; Dr. Carter reviewed 77 files; and Mr. Tooley reviewed 13 files [Doc. 477, pp.5-6]. The Government also provided these experts with "related prescription data" from the Tennessee Controlled Substance Monitoring Database, which is maintained by the Tennessee Department of Health [Doc. 477, p.7]. The experts created written opinions on the files they reviewed, and the Government disclosed these reports to the Defendants [Doc. 477, p.7].

The Government also used the Drug Enforcement Agency's National Drug Intelligence Center, Document and Media Exploitation Branch ("DOMEX") to extract certain data from patient files seized from the Lenoir City and Knoxville pain clinics in this case and to quantify and summarize the data from these files [Doc. 477, p.7]. The Government selected 444 patient

[1] The Court takes the factual background for these issues primarily from the Government's response [Doc. 477].

files based upon its own criteria, such as whether the patient had died, claimed disability, had been indicted in a related case, was an undercover agent, or had been discharged from one clinic and sent to an associated clinic [Doc. 477, p.8]. An additional 256 patient files were randomly selected [Doc. 477, p.8]. Analysts from DOMEX manually entered the data from these 700 patient files and then provided summaries of specific data points requested by the Government: Summary of Weight by Drug, Summary of Drug Weights by Provider, Location and Demographics of Patients, Provider Summary Tables, Payments and Referrals, and Drugs Prescribed by Provider [Doc. 477, p.8]. Logan Lake and Jon West, the analysts who oversaw the creation of the "DOMEX report" in this case, do not hold a medical degree or have any medical training or experience [Doc. 477, p.8].

Relying on *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993), the Defendants argue [Doc. 444] that the Government's medical experts should be excluded because the methodology used in selecting the patient files they reviewed is flawed and the sample pool of patient files is unrepresentative. They maintain that because the Government "cherry picked" the patient files reviewed by the medical experts, the experts' opinions are skewed to support the Government's theory of the case and any extrapolation to the case as a whole from their review of this flawed sample will mislead or confuse the jury. They also argue that the medical experts' opinions are not relevant to whether the Defendants acted like conventional drug dealers in this case. Accordingly, the Defendants assert that the Government's medical experts must be excluded or, at least, limited to the files they each individually examined.

With regard to the DOMEX report, the Defendants also argue that the unrepresentative selection of patient files analyzed renders the report unreliable. They ask the Court to exclude the report or to order the Government not to extrapolate to the whole patient

population and to instruct the jury that it may not extrapolate from the report to all of the patients in the clinic.

The Government admits [Doc. 477] that it selected all of the patient files reviewed by its experts and most of the files analyzed in the DOMEX report, but it contends that this does not create a *Daubert* issue. It argues that the manner in which the files were selected does not affect the reliability of the experts' opinions about the files that each expert has reviewed. The Government argues that in addition to providing their expert medical opinion about the files that they have each personally reviewed, its medical experts may properly give an opinion on the examination and prescribing practices of the clinic medical staff in light of the overall clinic environment. It maintains that its medical experts may also properly testify about the generally acceptable standards for issuing prescriptions.

The Government also argues that the DOMEX report is not an expert report subject to *Daubert* analysis but, instead, is a summary pursuant to Federal Rule of Evidence 1006. It asserts that the DOMEX report is admissible, because it summarizes a large volume of patient files, which cannot be conveniently introduced at trial. The Government maintains that the patient files have all been provided in discovery and that each patient file would be individually admissible. It also contends that the summaries contained within the report are accurate and not prejudicial and that the report will be introduced by an analyst, who supervised its preparation. Thus, the Government argues that the DOMEX report is admissible under Rule 1006. It asserts that if the Defendants object to the method used to create the report, their remedy is to cross-examine the analysts about the sample selection and size at trial.

The Court heard argument on these issues at a motion hearing on May 10, 2019. Assistant United States Attorneys Tracy L. Stone and Kelly Kathleen Pearson appeared on behalf of the Government. Attorneys Charles C. Burks, Jr., and Loretta G. Cravens represented

Defendant Hofstetter. Attorneys Christopher J. Oldham and Mark E. Brown represented Defendant Newman. Attorneys Randall E. Reagan and Cullen Michael Wojcik represented Defendant Clemons.[2] The Defendants were excused from appearing at the hearing.

Mr. Brown argued on behalf of the Defendants that the testimony of the Government's experts is neither reliable, nor relevant. He asserted that the Government's theory of the case is that the medical providers working at the clinics at issue were essentially drug dealers with prescription pads and that not one patient received care that was within the scope of professional practice or for a legitimate medical purpose. Mr. Brown maintained that the opinions of the Government's medical experts are not reliable, because they reviewed a small percentage of patient files, all of which were chosen by the Government. He agreed that the Government's medical experts could properly give an expert opinion about the care of a specific patient whose file the expert reviewed. However, he argued that the Government's theory in this case is that the entire clinics are run illegally, and that due to the statistical unreliability of the method of choosing the patient files, the Government's experts cannot give a valid expert opinion about the patient care at the clinics as a whole.

Mr. Oldham argued that there are two problems with the Government's proposed medical experts. One issue is that the expert reports disclosed by the Government do not provide the standards upon which Dr. Blake and Dr. Wilke based their opinions and provide only a brief statement of the standard used by Mr. Carter. Mr. Oldham argued that defense counsel need a *Daubert* hearing in order to question the Government's experts about the standards that form the basis of their opinions. However, he acknowledged that the Defendants are not challenging the credibility or the qualifications of the Government's medical experts. Mr. Oldham asserted that if

[2] Attorney Christopher Rodgers participated by telephone on behalf of Defendant Holli Womack, who has not joined in this motion.

the experts are limited to testifying about the specific patient files that they reviewed, then defense counsel can cross-examine them about those files.

Mr. Oldham argued that the more important issue is whether the Government's medical experts should be allowed to extrapolate to the clinics as a whole, based upon their review of an invalid statistical sample. He stated that a truly random sample is necessary in order to extrapolate to the entire group. He noted that the files selected by the Government for the experts to review were almost exclusively those of patients who were indicted. Thus, he contends that the sample was weighted to yield the conclusion that the Government wants. Mr. Oldham contended that the Court, as the gatekeeper, must make a threshold ruling that this data is not reliable in this case. He argued that the average juror does not understand statistics and, thus, it would be very difficult for defense counsel to expose the flaws in the expert's extrapolation through cross-examination. Mr. Oldham agreed that a *Daubert* hearing would not be relevant to the issue of the reliability of the sample, because the Government admits that it selected the patient files. He asked the Court to rule that while the Government's medical experts can testify on their opinions about the individual charts that they reviewed, they cannot extrapolate to all the patients or to the clinic as a whole.

Mr. Brown argued that the DOMEX report is also inadmissible, even as a summary, because the manner in which the patient files included in the summary were selected is flawed. He argued that this tainted selection yields an inaccurate result.

AUSA Stone responded that there is no need for a *Daubert* hearing in this case. He said the Government's experts will base their opinions primarily on the patient files they reviewed and will not extrapolate to the entire patient population based upon those files. He acknowledged that the experts may have "signaled extrapolation" in the reports disclosed to the Defendants, but he said that did not mean that the Government would ask the experts to extrapolate at trial. AUSA

Stone clarified that the medical experts, however, should be allowed to give opinions about the clinics in this case, based upon other facts in evidence. He stated that Drs. Blake and Wilke both run pain clinics and, thus, are qualified to know the difference between a legitimate and an illegitimate clinic. Moreover, AUSA Stone argued that the Government's medical experts will review the same fifteen (15) files reviewed by the Defendants' medical expert, which files he asserted "are fair game for extrapolation" by the Government's medical experts, based upon defense counsel's contention that these files are randomly selected.

With regard to the DOMEX report, AUSA Stone said that 444 patient files were selected based upon certain categories relevant to the Government's theory of the case. He said the Government wanted an equal number of randomly selected files, but, due to impending deadlines, they had to limit the randomly selected files to 256, for a total of 700 files. He argued that there should be no challenge to extrapolation from the 256 randomly selected files.

Counsel for both parties agreed that there was no need for a *Daubert* hearing, if the Court ruled that the Government's medical experts may give an expert opinion on the patient files that they each reviewed but may not extrapolate to the entire patient population. Mr. Oldham requested that if the Government's experts reviewed other materials pretrial, such as summaries or incident reports, that the Government provide a supplemental expert disclosure, stating the other materials reviewed by the experts. AUSA Stone responded that the Government was aware of the new deadline for supplemental expert disclosure imposed by the Court. Mr. Burks objected to the Government's medical experts providing an expert opinion, based upon facts that come into evidence during the trial, with regard to the ultimate issue of whether the instant pain clinics were pill mills. He argued that while the Government's medical experts can talk about the characteristics of pill mills, they cannot apply those characteristics to the clinics in this case. AUSA Stone encouraged the Court to rule conservatively on this issue and to let the District Judge

rule on what the experts can say about the facts that come in at trial. He stated that the Government will be careful of straying into testimony on the ultimate issue in order not to create an appealable issue.

The parties also agreed that a *Daubert* hearing was not necessary with regard to the DOMEX report. Mr. Oldham and Mr. Burks stated that by agreeing that no *Daubert* hearing is necessary, the Defendants were not waiving their opportunity to file a motion *in limine* challenging the DOMEX report at a later time.

II. ANALYSIS

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony: "A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise, if:"

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue,
>
> (b) the testimony is based upon sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

The trial judge must act as a gatekeeper, admitting only that expert testimony that is relevant and reliable. *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579, 589 (1993). With regard to scientific knowledge, the trial court must initially determine whether the reasoning or methodology used is scientifically valid and is properly applied to the facts at issue in the trial. *Id.* To aid the trial court in this gatekeeping role, the Supreme Court has listed several key considerations: (1) Can or has the scientific knowledge been tested, (2) Has the given theory or technique been

published or the subject of peer review, (3) Does a known error rate exist, and (4) Does the theory enjoy general acceptance in the particular field. *Id.* at 592-94.

Although *Daubert* focused on the admissibility of scientific expert opinions, the trial court's gatekeeping function applies to all expert testimony, including that based upon specialized or technical, as opposed to scientific, knowledge. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 147-48 (1999); *Berry v. City of Detroit*, 25 F.3d 1342, 1350 (6th Cir. 1994). The trial court's objective "is to make certain that an expert, whether basing testimony upon professional studies or personal experience, employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Kumho Tire*, 526 U.S. at 152. Although the general principles established in *Daubert* apply to all experts, the enumerated considerations may or may not apply to a particular non-scientific expert. *Id.* at 149. The trial judge enjoys broad discretion in determining whether the factors listed in *Daubert* reasonably measure reliability in a given case. *Id.* at 153. Finally, expert testimony must be relevant, as well as reliable. *Daubert*, 509 U.S. at 589; *United States v. Jones*, 107 F.3d 1147, 1156 (6th Cir.), *cert. denied*, 521 U.S. 1127 (1997). With this framework in mind, the Court turns to the issues surrounding the admissibility of the opinions of the Government's proposed medical experts and its DOMEX report.

A. Expert Testimony of Government's Medical Experts

The bulk of the issues raised by the Defendants with regard to admissibility of the Government's experts' opinions were resolved at the May 10 motion hearing. The Court finds that the main issue initially raised by the Defendants, which is whether the Government's medical experts can extrapolate from the patient files they reviewed to the patient population as a whole, is resolved by agreement of the parties. The Government agrees that its medical experts will testify about the patient files they each reviewed but will not extrapolate from those files to the patient

population as a whole or to the overall operation of the clinics in this case. The Defendants agree that this limitation satisfies their objection to extrapolation due to methodology of selection of the patient files. The Court also finds that the Defendants concede that they are not challenging the qualifications or credibility of the Government's experts and that they agree that cross-examination is the appropriate method to challenge the experts' opinions on the patient files they individually reviewed. Thus, the Court finds no need for an evidentiary hearing with regard to these issues.

However, the Court finds that some ambiguity exists with regard to whether the Government's medical experts may give opinions about the legitimacy of the clinics in this case, based upon their consideration of the facts that come into evidence at trial. The Defendants argue that such testimony would invade the province of the jury by opining on the ultimate issue, in violation of Rule 704. The Government contends that particularly Drs. Blake and Wilke, who themselves run pain management clinics, have the expertise to give opinions on whether a pain clinic is being run appropriately or is actually a pill mill. The Government encourages the Court to forego ruling on this issue, the contours of which are more appropriately shaped by District Judge Varlan within the context of the trial. The Court finds that while the specific details of this issue must be decided during the trial, the evidentiary rules and case law provide parameters to guide the parties as the issues develop.

First, the Court observes that an "expert may base an opinion on facts or data in the case that the expert has been made aware of or personally observed." Fed. R. Evid. 703; *see also* Advisory Committee Notes to Fed. R. Evid 703 (observing that experts may "attend the trial and hear the testimony establishing the facts" upon which he or she bases an opinion). Moreover, with the exception of an opinion on the defendant's intent, the opinion of an expert "is not objectionable just because it embraces an ultimate issue." Fed. Rule Evid. 704(a)-(b). "An expert may not opine on the overarching question of guilt or innocence[.]" *United States v. Volkman*, 797 F.3d 377, 388

(6th Cir.), *cert. denied*, 136 S. Ct. 348 (2015). "When the rules speak of an expert's testimony embracing the ultimate issue, the reference must be to stating opinions that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue." *Berry v. Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994), *cert. denied,* 513 U.S. 1111 (1995). In other words, while an expert may testify about a fact that relates to the ultimate issue, the expert may not give a legal conclusion. *Id.*

"Expert testimony on whether prescriptions are medically appropriate has long been the norm in controlled-substance prosecutions." *United States v. Lang*, 717 F. App'x 523, 534 (6th Cir. 2017) (holding that medical doctor properly gave opinion testimony on patient files that he reviewed) (citing *United States v. Word*, 806 F.2d 658, 662-64 (6th Cir. 1986) and *United States v. Hughes*, 895 F.2d 1135, 1144 (6th Cir. 1990)). In *United States v. Volkman*, our appellate court held that the opinions of medical experts that prescriptions issued by the defendant physician had no legitimate medical purpose did not violate the province of the jury. 797 F.3d at 389-90. The Court also upheld the testimony by a medical doctor and a pharmacist on "the standard of care and the evaluation of certain drug combinations or quantities," determining that "both experts applied their understanding of the standard-of-care to a limited sample of facts." *Id.* at 390; *see also United States v. Quinones*, 536 F. Supp. 2d 267, 274 (E.D.N.Y. 2008) (observing that, in order to convict a medical professional of a violation of § 841(a)(1), the government must necessarily prove "what the medical profession would generally do in the circumstances"). Finally, in *United States v. Hughes*, the medical expert responded to hypothetical questions by "offer[ing] his expert opinion that certain practices, established by other evidence, were beyond the scope of legitimate medical practice." 895 F.2d at 1145. However, the court pointed out that the expert "answered only hypothetical questions about medical practice." *Id.* at 1145, n.14.

From these cases, the Court generally distills that the Government's medical experts may be permitted to offer opinions not only about whether specific prescriptions were issued with a legitimate medical purpose, but also about whether certain conditions or circumstances at the clinics (as established by the evidence introduced at trial) were medically appropriate or within the scope of legitimate medical practice. However, the Court agrees with the Government that the admissibility of specific testimony is a determination best made by the District Judge in the context of the trial.

Accordingly, the Court finds that a *Daubert* hearing is not necessary in this case and that the parties agree that the Government's medical experts will not extrapolate from the patient files that they reviewed to the patient population as a whole.

B. Admissibility of Government's DOMEX Report

The Court also finds that the parties agreed that the admissibility of the DOMEX report was not an appropriate subject for a *Daubert* hearing. The Court finds that the DOMEX report is not an expert report but is instead a summary of other admissible evidence, i.e. a portion of the patient files. Rule 1006 permits a party to "use a summary, chart, or calculation to prove the content of voluminous writings, recordings, or photographs that cannot be conveniently examined in court." Fed R. Evid. 1006. Use of such summary evidence is contingent upon the party offering the summary making the evidence upon which it is based (either originals or duplicates) "available for examination or copying, or both, by other parties at a reasonable time and place." *Id.* The undersigned has recently held [Doc. 558] that the Government has provided electronic copies of all of the patient files to the Defendants and has provided defense counsel with a reasonable opportunity to inspect the original patient files.[3]

[3] In the interest of fairness, the Court required the Government to permit defense counsel to inspect the patient files for twelve additional hours by September 6, 2019.

In addition to the original evidence being voluminous and itself admissible and the evidence summarized being available to the other parties, the summary itself must be "'accurate and nonprejudicial.'"[4] *United States v. Bray*, 139 F.3d 1104, 1110 (6th Cir. 1998) (quoting *Gonzalez v. Great Lakes Steel*, 803 F.2d 250, 257 (6th Cir. 1986)). "This means first that the information on the document summarizes the information contained in the underlying documents accurately, correctly, and in a nonmisleading manner." *Id.* Here, the Defendants asked to reserve any challenge to the DOMEX report based upon Rule 1006 and asked to be permitted to raise any evidentiary challenges to the DOMEX report in a motion *in limine.* Accordingly, the undersigned makes no determination on whether the DOMEX report is accurate and not prejudicial in compliance with Rule 1006.

III. CONCLUSION

Based upon the parties' briefs and arguments, as well as the applicable case law, the Defendants' *Daubert* Motion to Exclude or Limit the Expert Testimony of Dr. James Wilke, Dr. John Blake, Michael Carter, and Gary Tooley and to Limit its Use of DOMEX Report [**Doc. 444**] is **GRANTED in part and DENIED in part** as follows:

(1) A *Daubert* hearing at which the Defendants challenge the methodology of the Government's medical experts or of the DOMEX report is not necessary or appropriate in this case, and the Defendant's request for a *Daubert* hearing is denied;

(2) The Defendant's request to limit the testimony of the Government's medical experts is granted. The Government's medical experts are not permitted to extrapolate to or draw conclusions about the care of the clinic patients as a whole based solely upon their review of the patient files selected by the Government;

[4] The Court notes that *Bray* includes a fifth requirement that the party offering the summary lay a proper foundation for its admission through the testimony of the individual who supervised the preparation of the summary. 139 F.3d at 1110.

(3) The Government's medical experts with expertise in the area of pain management clinics may testify about the standard of care for healthcare providers in pain management clinics;

(4) The Government's medical experts may testify generally as to whether the practices at the pain management clinics in this case, as revealed by the evidence at trial, were medically appropriate or within the scope of legitimate medical practice. However, the admissibility of specific testimony by the Government's medical experts is a matter for the District Judge to determine at trial;

(5) The Government's medical experts may also testify about the expert opinions of the Defendants' medical experts; and

(6) The Defendants are not precluded from filing a motion *in limine* challenging the DOMEX report.

IT IS SO ORDERED.

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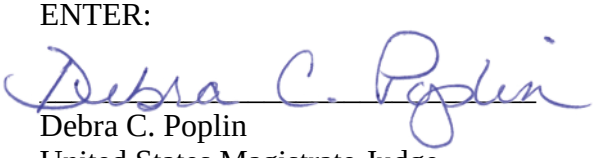

Debra C. Poplin
United States Magistrate Judge